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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,213	09/16/2003	Hassan Mostafavi	005513P021	3361

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EXAMINER	
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ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,213	MOSTAFAVI ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,58,59,62-79 and 81-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,58,59,62-79 and 81-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/4/09 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 49-58, 62-79 and 81-84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-21, 24, 31-43, and 53-60 of copending Application No. 10/664308. Although the conflicting claims are not identical, they are not patentably distinct from each other because determining the coordinates of the markers with respect to the beam isocenters is an obvious modification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7, 13-14, 16, 49-58, 62, 76-77, 82, 84, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461).

Mate et al. show a guided radiation therapy system. The radiation delivery source can be a linear accelerator, or any other type of radiation therapy device ([0034]). The radiation device has a machine isocenter associated with it. This is the isocenter of the radiation beam ([0035]). A plurality of markers are positioned in the target to mark the actual location of the target in the body. These markers define a target isocenter. The target isocenter is selected as part of a treatment planning procedure by a treatment planning system ([0054]). The position and orientation of each marker is obtained and used to determine the precise location of the target isocenter ([0036]-[0037]). The markers can be implanted in the patient, and delivered by an applicator needle ([0041]). The actual position of the target isocenter is compared to the position of the machine isocenter, and if they are spatially misaligned, the target can be moved relative to the machine isocenter. Once the target isocenter and machine isocenter are coincident, the radiation treatment is applied ([0039]). Determining the position manually would be a well known and obvious modification to one of ordinary skill in the art. Mate et al. fail to show using more than one imaging modality.

Cosman discloses a surgical positioning system. Cosman teaches that X-ray imaging can be used to further refine the positioning of the isocenter. The X-ray images can aid in determining the position of markers within the body. The use of X-ray

imaging further improves the accuracy of the alignment ([0064]-[0069]). Furthermore, the same imaging modality could be used. Cosman teaches the use of preoperative CT scanning ([0064]) and the use of interoperative CT scanning as well ([0065]). These imaging systems are located on different machines, one being used for planning the treatment and one being used for the actual treatment. As indicated by applicant's specification ([0064]), various configurations are known in the art and may be used, including imagers located on a gantry or as part of a treatment table. Cosman also teaches that both the treatment machine and the patient can be moved to accomplish desired positional relationships ([0024]). The treatment machine is rotatable ([0025]). A multileaf collimator or any other type of known collimator can be used as well ([0026]). The angle and shape of the treatment beam can be controlled ([0043]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a second imaging system to align the patient and the treatment beam as taught by Cosman in the system of Mate et al. The use of a second imaging system will increase the accuracy of the alignment.

Claims 4 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) as applied to claim 1 above, and further in view of Jaffray et al. (US 2003/0007601).

Jaffray et al. disclose a radiation therapy system. Jaffray et al. teach that kV or MV imaging can be used to aid in lesion location ([0008]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Mate et al. with any imaging modality which will aid in the radiation therapy process, kV or MV imaging between two such possible imaging modalities which are known for aiding in lesion location.

Claims 8-9, 12, 78-79, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) as applied to claims 6 and 7 above, and further in view of Jang (US 5757953).

Jang discloses an automated method and system of region decomposition in digital radiographic images. Jang teaches that shape filtering and connected component analysis are used to decompose an image into meaningful subregions (column 11, lines 30-67). The median filters can be used to smooth the image (column 9, line 3). The details of the operation of median filtering are old and well-known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a median filter and connected component analysis as taught by Jang, in the combined system of Mate et al. and Cosman. One of ordinary skill in the art would have used these techniques to divide the image into useful regions, and to find the location of the markers in the images. In addition, by determining the location of markers in the image, the user would know which objects are not markers. It would be obvious to one of ordinary skill in the art to make sure that these objects would

then not be considered as markers, and would not be used for any further steps, such as during the alignment.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Jang (US 5757953) as applied to claim 8 above, and further in view of Gerig et al. (US 5446548).

Gerig et al. disclose a patient positioning and monitoring system. Gerig et al. teach the use of an epipolar line constraint (column 5, lines 19-43). Such a technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used an epipolar line constraint technique as taught by Gerig et al. in the combined system of Mate et al., Cosman, and Jang. One of ordinary skill in the art would use such a technique to aid in aligning the markers in the sets of images.

Claims 15, 63-72, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) as applied to claims 1 and 14 above, and further in view of Fitzpatrick et al. (US 6073044).

Fitzpatrick et al. disclose a method for determining the location in physical space of a point of a fiducial marker. Fitzpatrick et al. teach that a rigid body transform is necessary to register and align the coordinate systems of two imaging modalities

(column 1, lines 42-58). A rigid body transform technique is old and well known in the art.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a rigid body transform technique as taught by Fitzpatrick et al., in the combined system of Mate et al. and Cosman. When using two imaging modalities, such a technique will allow for the two imaging spaces to be properly registered and aligned, and thus the markers in the two images to be aligned. This will allow for the proper positioning adjustment to be determined and executed.

Also, it would have been obvious to have used the same angle for image as for a treatment beam, as this will reduce the amount of time between acquiring images and moving the treatment system into the proper location, because it is already in the proper location. A shorter time between imaging and treatment will prevent more motion from occurring in between, which would reduce the accuracy of the system.

Claims 73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) and Fitzpatrick et al. (US 6073044) as applied to claim 64 above, and further in view of Carol (US 5622187).

Carol discloses a method and apparatus for patient positioning for radiation therapy. Carol teaches that multiple positioning images can be acquired and a triangulation technique used (column 8, line 61-column 9, line 25).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have acquired images from different angles as taught by Carol in the combined system of Mate et al. and Cosman. Acquiring an image from more than one angle provides additional data that can be used for three-dimensional reconstruction. If the images were acquired at the same angle, this would not be possible.

Claims 85-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Cosman (US 2002/0065461) as applied to claims 1 and 58 above, and further in view of Ishikawa et al. (US 6398710).

Ishikawa et al. disclose a radiation dosimetry system. Ishikawa et al. teach the use of implantable devices which measure the radiation delivered to the target site (column 4, lines 25-50).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined system of Mate et al. and Cosman to measure the radiation dosage at the target site as taught by Ishikawa et al. Such techniques are well known in the art, and are commonly used in radiation treatment systems, as they allow the physician to determine the optimal radiation dose to treat the patient with, without damaging nearby healthy tissue.

Response to Arguments

Applicant's arguments filed 5/4/09 have been fully considered but they are not persuasive.

In regards to applicant's arguments regarding markers implanted into soft tissue of the body, examiner respectfully disagrees. Mate shows implanting markers within the patient using a needle applicator ([0041]). These markers can be imaged to determine the position of the markers relative to a tumor ([0063]). Cosman also teach implanting markers into a patient. The markers can be implanted into bone or tissue, and are radiopaque for visualization with x-ray imaging systems. This allows for further refinement of the treatment target position ([0067]).

In regards to applicant's arguments regarding x-ray imaging, examiner respectfully disagrees. Mate shows the use of CT imaging, while not going into much detail ([0054], [0062]). Cosman specifically teach using two x-ray imaging machines (80 and 81) aligned horizontally and vertically to image radiopaque markers implanted in tissue within the patient for the purpose of further refining target positioning. This allows for a more accurate alignment of the target within the patient to be treated and the LINAC device.

Various other related arguments are similarly disagreed upon, as detailed above, Mate and Cosman both show imaging markers implanted within soft tissue of the patient.

In regards to applicant's arguments that Ishikawa does not teach measuring radiation received by markers having coordinates determined relative to a first and

second beam isocenter, examiner respectfully disagrees. Ishikawa clearly shows measuring radiation during tumor treatment using an implanted device (column 4, lines 25-50). In combination with the other references in the 103 rejection, the claim limitations are met. Applicant's argument that Ishikawa only teaches imaging markers using radio frequency transmission signals is irrelevant in view of Mate and Cosman as relied upon in the 103 rejection.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737